OBJECTIVES: Anaemia is a frequent complication among patients with Chronic Kidney Disease (CKD). This retrospective, observational study quantifies healthcare resource utilization (HCRU) and costs associated with anaemia in an Italian cohort of CKD-NOD patients. **METHODS:** Administrative data and clinical laboratory files of 7 Italian LHUs from 2006 and 2011 were used to identify patients with CKD (stage3b, 4, 5) and anaemia. Included patients had anaemia (≥2 haemoglobin [Hb] measurements 1 week–3 months apart <13 g/dL for males, <12 g/dL for females) associated with CKD-NOD stage 3b, 4, or 5. HCRU included CKD-anaemia medications, laboratory tests, haematologist/cardiologist visits, and hospitalisations for CKD-anaemia or cardiovascular disease (CVD). Costs were calculated using Italian prices and tariffs. **RESULTS:** 1,654 patients were included. Overall, 542 (32.8%) of all 1,654 patients received anaemia medications during follow-up. The prevalence of anaemia medication use and number of prescriptions for these medications were higher at higher CKD stage, although the low numbers of patients in stage 5 (from 28.3% for stage 3b to 55.3.% for stage 5). ESAs were prescribed to 85.7% of CKD stage 5 patients whereas CKD stage 3b patients received mostly oral iron (60.2%). Patients receiving any anaemia-related medications had lower per patient-per year cost for all studied resources compared to patients not receiving any medications. For anaemia-related outpatient services [treated and not treated]: stage 3b costs per patient year were €61.86 and €65.46 respectively; €60.79 and €73.31 for stage 4; €63.40 and €81.26 for stage 5. For general visits: €175.87 and €194.61 for stage 3b; €152.32 and €186.73 for stage 4; €152.36 and €342.09 for stage 5. For CV hospitalizations costs were €1531.91 and €1740.88 for stage 3b; €1,152.27 and €2,194,06 for stage 4; €527.79 and €483.44 for stage 5. **CONCLUSIONS:** Anaemia management may help lower both anaemia-related outpatient services and CV complications costs.

PSY121

HEALTHCARE RESOURCE CONSUMPTION AND COST OF CARE IN PATIENTS WITH AUTOSOMAL DOMINANT POLYCYSTIC DISEASE (ADPKD) IN ITALY

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OBJECTIVES: To assess the consumption of healthcare resources in patients with polycystic kidney disease, and analyse related costs **METHODS:** Database analysis of administrative databases, containing information on beneficiaries of two Local Health Units, for around 2 million subjects. Data from all patients with polycystic kidney disease in the period January 2010 - December 2012 were analysed, the index-date was the date of diagnosis at hospitalisation; for patients on dialysis, index-date was the first day of dialysis during enrolment period **RESULTS:** 608 patients with polycystic kidney disease were enrolled (ICD-9 753.1), 11.2% were ADPKD patients. 1.5% of patients was ARPKD, in 16.3% genotype was not specified, and in the remaining ones the disease had not been classified.These four sub-populations were analysed, and the 68 ADPKD patients reported some differences from the overall population enrolled. Mean age in ADPKD group was 45.9 years, versus 57 of the entire sample, and the incidence of dialysis was 4-fold (29.4% compared to an overall 7.9%).1-year consumption of healthcare resources for the 20 dialysed patients with ADPKD was higher than in non-dialysed patients: 27.5 drug prescriptions compared to 15.2, and 27.6 recurrences to ambulatory care services compared to 5.1, respectively.Health expenditure for ADPKD dialysed patients was €36,999.30 per year, € 28,545.30 for ambulatory care (96% dialysis-related), € 4'695.45 for hospitalizations and € 3'758.55 for drugs.For non-dialysed ADPKD patients, total expenditure was €4'534.79, with € 2,017.44 for hospitalisations; drugs cost was € 1,998.60 - 5% of which for anti-hypertensives - and ambulatory care services amounted to € 518.75 **CONCLUSIONS:** The reported higher incidence of dialysis - and a lower mean age - highlight the severity of PKD connected to the autosomal dominant type, that eventually leads to an annual burden for NHS of about € 37'000 for each ADPKD dialysed patients

PSY122

PATIENT UNDERSTANDING AND ATTITUDES ABOUT BIOSIMILARS: AN INTERNATIONAL CROSS-SECTIONAL SURVEY

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OBJECTIVES: To understand current levels of awareness, usage, and knowledge of biosimilars. **METHODS:** Interviews (10 to 20 minutes of close-ended questions) were conducted online in adults categorized as: 1) Diagnosed: patients with Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriasis, breast cancer, lung cancer, colorectal cancer, or non-Hodgkin's lymphoma; 2) Diagnosed Advocacy: individuals with these diseases who participated in patient support groups; 3) Caregiver: has a loved one with these conditions and is involved in medical decisions; or 4) General Population: aged 18 to 64 years without (nor loved ones with) these conditions. Groups were analyzed using the column proportions test with a 95% confidence interval. **RESULTS:** A total of 3,198 individuals responded. Awareness about biologic therapies, defined as the percentage of respondents reporting at least a general impression of biologics or that they knew the term "biologic", was significantly higher in the Diagnosed, Diagnosed Advocacy, and Caregiver groups (45-78%) than the General Population (27%; $P < 0.05$). Across all groups, awareness of biosimilars was low with only 6% of respondents from the General Population reporting at least a general impression of biosimilars, although this was significantly higher among respondents in the Diagnosed Advocacy group (20-30%; $P < 0.05$). Several gaps in respondents' knowledge about biosimilars were noted including safety, efficacy, and access to these agents. Respondents had generally positive perceptions of clinical trials although some barriers to participation were identified such as concerns about side effects, assignment to placebo rather than an active treatment, and time commitments. **CONCLUSIONS:** As more biosimilars are becoming approved, this study reinforces that there is still an immediate need to provide education to all stakeholders about general biosimilar education and biosimilar clinical trials. These efforts will support patient choice and ensure that educated and informed decisions are made about the use of biosimilars.

PSY123

DIAGNOSIS OF LIVER DISEASES AMONG INDIVIDUAL WITH HEPATIC DYSFUNCTION DETECTED BY ANNUAL HEALTH CHECKUP BASED ON CLAIMS DATA IN JAPAN

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OBJECTIVES: Objective of this study is to evaluate the diagnosis of liver diseases among individuals who were detected hepatic dysfunction by the annual health checkup (Kenshin) in Japan. **METHODS:** Annual health checkup data and claims data based on Japan Medical Data Center (JMDC) were used to evaluate the diagnosis of liver disease by ICD10. Individuals who had annual health checkup in 2012 and their associated claims data were merged by unique identifiers. Individuals (18≤age≤64) with ALT≥30(IU/L) were defined as hepatic dysfunction. Confirmed diagnoses of liver diseases were evaluated. The time to diagnosis after the annual health checkup and the diagnosis with liver disease by ALT levels(IU/L) (30<ALT<60 and 60=<ALT) were assessed. **RESULTS:** Among 57,059 individuals (ALT >30) without diagnosis of any liver disease in the preceding 12 month of the annual health checkup, 7500(13.1%) of individuals were visited physician office within one year their after annual health check-ups(30<ALT<60:5,185 and 60=<ALT:2,315). Among individuals visited physician office, 4,379(58.4%) of individuals were diagnosed with liver diseases; 30<ALT<60: 2,733(52.7%) and 60=<ALT: 1,646(71.1%). Fatty liver (21.4%) was major diagnosis followed by alcoholic hepatic disease(3.0%), virus hepatitis(3.1%), hepatic fibrosis or cirrhosis(0.5%) and liver cancer (0.3%). The detection rate of each liver disease are higher in individuals with 60=<ALT compared to individuals with 30<ALT<60. Time to diagnosis was also faster among individual with 60=<ALT compare to individuals with 30<ALT<60 (log-rank test: $p < 0.0001$). **CONCLUSIONS:** The proportion of individuals diagnosed with liver disease was relatively low considering the number of individuals with hepatic dysfunction detected by the annual checkup. Individuals with higher ALT levels were more likely to be diagnosed with liver disease.

PSY124

THE ITALIAN 648/96 LIST: APPROVALS, REJECTIONS AND METHODS IN AIFA'S EVALUATION PROCESS BETWEEN JANUARY 2013 AND MAY 2015

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OBJECTIVES: Through the Italian off-label/compassionate use procedure, regulated by Law 648/96, the Technical Committee of AIFA (CTS) can include a given medication (among innovative drugs authorised abroad, but not in Italy, drugs which have not yet received an authorisation but have undergone clinical trials, and drugs to be used for a therapeutic indication different from the authorized one) in an official list, allowing it to be prescribed at the charge of the National Health System (NHS). This study aimed to assess AIFA's approach, by reviewing approvals, rejections and methods followed by AIFA for its decisions. **METHODS:** Reports of CTS meetings from January 2013 to May 2015 were reviewed, checking number and characteristics of drugs under evaluation, and analyzing each single decision taken by CTS. The impact of 648 on pricing and reimbursement decisions was also analysed (both in terms of price and time) **RESULTS:** Out of 103 applications, 37 (35,9%) received a positive evaluation, 54 (52,4%) a negative evaluation and 12 (11,7%) a conditional approval. The main therapeutic areas represented were oncology/onco-haematology with 29 requests (28,2%), followed by paediatrics with 12 requests (9,2%), non-oncological haematology and cardiovascular, both with 9 requests (6,9% each), neurology and ophthalmology. Several rare disease compounds have been evaluated. Analysis indicated that the drivers for the inclusion in the 648 List were the presence of strong clinical data, the lack of therapeutics alternatives in the Italian market, the rare disease condition and the paediatric indication. **CONCLUSIONS:** In the last two-and-a-half years, 49 indications have been approved, ensuring new important safe and efficacious therapeutic options. This analysis shows the important role of the Italian Law 648/96, a precious tool for patients to be treated with a drug, with strong clinical and safety data, waiting for the whole Italian regulatory process to be completed.

PSY125

MARKET ACCESS TRENDS IN RARE DISEASE APPROVALS IN EUROPE FROM 2005 TO 2014

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OBJECTIVES: Over the past decade, the European Medicines Agency (EMA) has granted regulatory approval to over 75 rare disease therapies and acknowledged hundreds of pipeline compounds with rare disease regulatory designation. In Europe, market access for new technologies is predominantly dependent on regulatory and country-specific health technology assessments. Therefore, the purpose of this analysis was to examine how the impact of United Kingdom (UK) health policies affected the market access of rare disease technologies during 2005-2014. **METHODS:** A list of approved rare disease health technologies was constructed utilizing publically available data from the EMA. The technologies had to adhere to European specific rare disease designation guidelines for study inclusion. Secondly, the list was cross-referenced with the National Institute of Health and Care Excellence (NICE) repository of appraised technologies. Information extracted from the NICE repository included: complete appraisal document, incremental cost-effectiveness ratio (ICER), and final agency recommendation. Thirdly, an Excel worksheet was created and several descriptive techniques were used for trend analysis, including: calculating the proportion of NICE appraisal of EMA approvals, EMA/NICE annual approval rate, and ICER range across NICE appraisals. **RESULTS:** A Positive trend in rare disease technology regulatory approvals from 2005-2014 was observed in Europe (average increase of 1.2 approvals/year), with the highest number of approvals occurring in 2014 (total approvals = 15). The trend in NICE approvals during this period remained flat at an average of 0.2/year (5 currently under review in 2014), despite the number of appraisals increasing an average of 0.5/year.